

MEDICAL LABORATORY BOARD MINUTES

Date: January 15, 2004

Time: 9:00 a.m., CST

Location: Cumberland Room
Ground Floor, Cordell Hull Building
425 Fifth Avenue North
Nashville, TN 37247

Members Present: Kelly S. Terry, Medical Technologist, Chairperson
Jere Ferguson, MD
Charles R. Handorf, MD
Edward McDonald, MD
Martha Duncan, Medical Technologist
Mary Anne Giannini, Medical Technologist
Sharon Hargrove, Medical Technologist
Linda Lahr, Medical Technologist
Alison McDonald, Cytotechnologist
Debbie Stinnett, Medical Technologist

Members Absent: Dennis Carter, MD
Delores Voigt, MT Hospital Administrator
Monya Faye Pryor, Citizen Representative

Staff Present: Lynda S. England, Medical Technologist, Director
Cheryl H. Thacker, Medical Technologist, Consultant
Robbie Bell, Health Related Boards Director
Jerry Kosten, Rules Manager
Robert Kraemer, Jr., Advisory Attorney
Julia Daniels, Medical Technologist Consultant/ Surveyor,
East Tennessee Regional Office
Sandra S. Bogard, Medical Technologist Consultant/Surveyor,
Middle Tennessee Regional Office
Irmgard Brown, Medical Technologist Consultant/Surveyor,
Middle Tennessee Regional Office
Karon Daniels, Medical Technologist Consultant/ Surveyor,
West Tennessee Regional Office

Staff Absent: Mary Hamblen, Medical Technologist Consultant/Surveyor
West Tennessee Regional Office
Onezean Otey, Jr., Medical Technologist Consultant/Surveyor,
East Tennessee Regional Office

Quorum: A sufficient number of board members were present to constitute a quorum.

Election of Board

Chair and Vice-Chair: Dr. Handorf nominated Ms. Terry to continue as chairperson. A second to the motion was made by Dr. Ferguson. The motion carried. Ms. Giannini nominated Dr. Ferguson to continue as chairperson. A second to the motion was made by Dr. McDonald. The motion carried.

Presiding Officer: The meeting was called to order by Ms. Terry at 9:08 a.m. Board Members introduced themselves to the audience.

Board Minutes:

A motion to approve the October 16, 2003 full board minutes with the noted changes on page two, paragraph two was made by Ms. Stinnett. A second to the motion was made by Dr. Ferguson. The minutes were approved.

A motion to approve the Personnel & Education minutes from the October 15, 2003 meeting was made by Ms. Hargrove. A second to the motion was made by Ms. Stinnett. The minutes were approved.

Board Report-Personnel & Education Committee:

Linda Lahr, MT
Committee Chair

Ms. Lahr presented report of actions from the Personnel & Education Committee meeting held on January 14, 2004. A motion to accept this report was made by Ms. Stinnett. A second to the motion was made by Ms. Duncan. The motion carried and the Committee actions were approved.

Board Report-Tennessee Professional Peer Assistance Program:

Leanne Busby DSN, RNC-State Director

Ms. Busby made the report to the board concerning activities of the Tennessee Professional Peer Assistance Program relative to medical laboratory professionals.

There were two (2) individuals referred by the staff consultant to be evaluated by this advocacy program. The complete report is on file in administrative office. A motion to accept this report was made by Ms. Duncan, with a second to the motion by Ms. McDonald. The motion carried.

The board discussed the renewal of the contract with Tennessee Professional Peer Assistance. The current contract with this agency will expire in June of 2004. Ms. Terry, Dr. Handorf, and Ms. Hargrove will meet with Ms. Busby to discuss the advocacy program.

Board Report-Rules:

Jerry Kosten-Rules Manager

Rules Amendments:

Mr. Kosten reported on a rulemaking hearing held December 30, 2003 concerning the following amendments:

1-Rule 1200-6-1-.24(1), Rules for Medical Laboratory Personnel concerning the qualifications of the cytotechnologist.

2-Rule 1200-6-3-.02(3)(a) Rules for Medical Laboratories concerning the renewal of facility and collection station licenses. The renewal cycle would begin on the anniversary date of the issuance of the original license to each facility. The cycle would still be a 12 month cycle beginning in 2005.

3-Rules 1200-6-1-.15(3) & 1200-6-3-.05(3) Rules for Medical Laboratory Personnel & Rules for Medical Laboratory Facilities regarding the issuance of Order Modifications.

4-Rule 1200-6-1 & 1200-6-3 Rules for Medical Laboratory Personnel and Rules for Medical Laboratory Facilities regarding Orders of Compliance.

5-Rule 1200-6-1 & 1200-6-3 Rules for Medical Laboratory Personnel & Rules for Medical Laboratory Facilities regarding a required Board appearance at the end of a disciplinary period.

There were no comments presented to Mr. Kosten during the rulemaking hearing.

A roll call vote was taken with all members present saying aye. Dr. Handorf made a motion to adopt the amendments with a second to the motion by Ms. Giannini. The motion carried.

Authorize Rulemaking Hearing:

Mr. Kosten made a request to the board concerning the authorization of a rule making hearing for the following proposed rules amendments proposed to be held on the 19th day of March 2004:

- 1) Rule 1200-6-1-.14(3) Rules for Medical Laboratory Personnel regarding the issuance of trainee permits to students enrolled in a board approved training program regarding the trainee permit be on site in the clinical rotation arena during the time of the rotation.

- 2) Rule 1200-6-1-.20(4)(e)4(iii & iv) Rules for Medical Laboratory Personnel regarding proficiency testing language clarification.
- 3) Rule 1200-6-3-.07(1)(a)3 & 1200-6-3-.08(1)(d)10 Rules for Medical Laboratory Facilities regarding clarification of language.
- 4) Rule 1200-6-3-.09(3)(a) Rules for Medical Laboratory Facilities regarding clarification of language.

A motion to authorize the rulemaking hearing was made by Dr. Handorf with a second to the motion made by Ms. Duncan. The motion carried.

Contested Case:

Daniel P. Walker
Medical Technologist-Supervisor
Nashville, TN
License#13028

The attorney for Mr. Walker requested a continuance to be held at a later date.

Ratifications:

The following items were presented to the Board for ratification per staff, state surveyor or facility request:

- 1) Exemptions for point of care testing procedures (POCT) in a licensed facility (See Attachment 1).
- 2) Initial licenses for Clinical Laboratory Facilities (See Attachment 2).

Board Director's Report/Discussion:

Lynda S. England BS MT(ASCP)
Director

Ms. England reported several items to the Board members including administrative office statistics, contact with TNPAP for peer assistance services, upcoming rulemaking hearings, newsletters projects, legislative actions, investigations/consultants, website updates, 2004 Board meeting dates, and facility closures.

A motion to accept Ms. England's report was made by Ms. Hargrove with a second to the motion by Ms. Stinnett. The motion carried.

Direct More Than Three (3) Labs
Rule 1200-6-3-.13(5) Medical Lab Facilities

No requests have been presented to the administrative office for review this quarter.

Reinstatement of License

No licenses were reinstated during this meeting.

Reports/Discussion

Regional Consultant/Surveyor - Proficiency Testing (PT)
Complaints on Licensed Laboratory Facilities

- A. **East Tennessee Regional Office-** Julia Daniels, Consultant II/Surveyor
Onezean Otey, Jr., Consultant I/Surveyor

Unsatisfactory or Unsuccessful Proficiency Testing:

In December 2003, two (2) licensed facilities had unsuccessful participation in proficiency testing events: facility #1 had one (1) SGOT testing event that was unsuccessful and facility #2 demonstrated unsuccessful participation with compatibility testing scores. Both facilities returned an acceptable plan of correction (POC) to the surveyor.

A motion to accept this report was made by Ms. Stinnett. A second to the motion was made by Dr. Handorf. The motion carried.

Complaints:

The East Tennessee Regional Office has conducted zero (0) complaint investigations from October through December 2003.

- B. **Middle Tennessee Regional Office-** Sandra S. Bogard, Consultant II/Surveyor
*Irmgard A. Brown, Consultant I/Surveyor

* Ms. Brown submitted an amended report.

Unacceptable/Unsuccessful Proficiency Testing:

The number of licensed laboratories demonstrating a first occurrence of unsuccessful proficiency testing events (two out of three events) is four (4).

Facility #1: Susceptibility Testing -Acceptable Plan of Correction.

Facility #2: Compatibility Testing-Acceptable Plan of Correction
Bilirubin, Total-Acceptable Plan of Correction

Facility #3: Blood Gas (PO2)-Not Finalized (Plan of Correction)

Facility #4: Blood Gas (pH)-Not Finalized (Plan of Correction)
Blood Gas (PCO2)-Not Finalized (Plan of Correction)

The number of State licensed laboratories with second (2nd) occurrence of unsuccessful proficiency testing events: one (1).

Facility#1: Blood Gas (PO2)-Not Finalized (Plan of Correction)

Complaints:

The Middle Tennessee Regional Office has conducted zero (0) complaint investigations October through December 2003.

A motion to accept this report was made by Dr. Handorf with a second to the motion by Dr. McDonald. The motion carried.

- C. **West Tennessee Regional Office-** Mary Hamblen, Consultant II/Surveyor
Karon Daniels, Consultant I/Surveyor

Unacceptable/Unsuccessful Proficiency Testing:

The number of state licensed laboratories with a first occurrence of unsuccessful proficiency testing (two out of three or two in a row): zero (0).

The number of state licensed laboratories with second occurrence of unsuccessful proficiency testing (three out of four or three in a row): zero (0).

Complaint Investigations:

The West Tennessee Regional Office has conducted zero (0) complaint investigations October through December 2003.

A motion to approve this report was made by Dr. Handorf with a second to the motion by Ms. Giannini. The motion carried.

Health Related Board's Report/Discussion:

Robbie Bell, Director

Ms. Bell reported that the legislative session for 2004 began on Tuesday, January 13, 2004. All board chairs will receive faxed copies of the legislative actions for 2004 for review and comment.

A motion to accept this report was made by Dr. Handorf with a second to the motion by Dr. McDonald. The motion carried.

Office of General Counsel Report:

Robert J. Kraemer, Jr.
Advisory Attorney

Mr. Kraemer led the discussion of the following items:

- 1) Amend Rules 1200-6-1 & 1200-6-3 Regarding Order Modifications.
- 2) Amend Rules 1200-6-1 & 1200-6-3 Regarding Order of Compliance.
- 3) Amend Rules 1200-6-1 & 1200-6-3 Regarding Required Board Appearance at End of Disciplinary Period.

A motion to accept this report was made by Ms. Hargrove with a second made by Ms. McDonald. The motion carried.

Bureau of Investigations (BIV) Report:

Lea Phelps
Disciplinary Coordinator

Ms. Phelps was questioned about the payment of civil penalties and how they are dispersed. Ms. Phelps responded by saying that the civil penalty fees are paid to the investigations department and then designated to the proper Board.

A motion to accept this report was made by Dr. Handorf with a second by Ms. Duncan. The motion carried.

Office of Health Licensure & Regulation:

Judy Eads, RN
Assistant Commissioner of Health

Ms. Eads did not make a report at this time.

Financial Report:

Lisa Tittle
Fiscal Officer

Ms. Tittle did not make a report at this time.

Waived Testing Procedures:

Additions/Deletions from- **1-Point of Care List**
2-Health Fair/Health Screen List.

No requests have been made to the program area administrative office for additions or deletions to the waived test procedure list for either point of care or health fair/health screen programs.

Point of Care Task Force

This task force continues to meet but no inquiries were made to the board during this meeting.

Review Eligibility of Medical Laboratory Director

Rebecca Berry, PhD – Buda, TX – Director-Cytogenetics

Ms. Thacker informed the Board that Dr. Berry's file was complete and she has met the requirements for a Director of Cytogenetics by possessing a PhD and national boarding in clinical cytogenetics with the American Board of Medical Genetics. Ms. Giannini motioned to approve this request for licensure. A second to the motion was made by Ms. Hargrove. The motion carried.

Statement of Next Meeting

The next meeting will be held on April 15, 2004 at 1 p.m., CDT in the Cumberland Room, Ground Floor, Cordell Hull Building, 425 Fifth Avenue North, Nashville, TN 37247-1010.

Record of Adjournment

With no further business to discuss, the meeting was adjourned at 12:22 p.m. on a motion properly presented by Ms. Giannini and seconded by Ms. Duncan. The motion carried.

Kelly S. Terry, MT
Board Chairman

Date

REQUEST FOR EXEMPTION-POINT OF CARE TESTING PROCEDURES

1. Dynacare Tennessee
1924 Alcoa Highway
Knoxville, TN 37920

Facility Representative: Jacqueline Christie, MT(ASCP), CLSup
Point of Care Coordinator

This request is for the following personnel in the locations listed to perform and report prothrombin time (PT) testing procedures utilizing the i-STAT instrument and methodologies:

Registered Nurses (RN's)-Critical Care Areas
Perfusionists & CRNA's –Surgical Suites
Paramedics-Patient transport to ER
Neo-Natal Nurse Practitioners-Patient transport to and within the ICN/IMCN.

A motion to approve this request was made by Dr. Handorf with a second to the motion by Ms. Giannini. The motion carried.

2. Horizon Medical Center
111 Highway 70 East
Dickson, TN 37055

Facility Representative: Nelma Crutcher
Director of Laboratory Services

This facility request was for Registered Nurses (RN's) to perform and report activated clotting times (ACT's) in the Heart Catheterization Laboratory (Cath Lab) utilizing the Hemochron, Jr., Signature Microcoagulation System and methodologies.

Ms. Duncan recused herself from this vote.

A motion to approve this request was made by Dr. McDonald. A second to the motion was made by Dr. Handorf. The motion carried.

Attachment 1
Medical Laboratory Board
Point of Care Exemption Requests
January 15, 2004

3. Williamson Medical Center
2021 Carothers Avenue
Franklin, TN 37067

Facility Representative: Carol J. Kelso, MT(ASCP)
Laboratory Administrator

This facility request was for Licensed Registered Nurses (RN's) & Licensed Practical Nurses (LPN's) to perform and report activated clotting times (ACT's) in the Cardiac Catheterization Laboratory utilizing the Helena Actalyke XL instrument and methodologies.

Ms. Stinnett recused herself from this vote.

A motion to approve this request was made by Dr. McDonald with a second to the motion by Dr. Handorf. The motion carried.

4. Maury Regional Medical Center
1225 Trotwood Avenue
Columbia, TN 38401

Facility Representative: Amy Sanders
Point of Care Coordinator

This facility request was for Certified Cardiovascular Technicians (CV's), Perfusionists, Licensed Physician's Assistants and Licensed Registered Nurses (RN's) to perform and report activated clotting times (ACT's) in the Cardiovascular Operating Rooms (CVOR), Cardiovascular Intensive Care Unit (CVICU) and the Cardiovascular Step-Down Unit (CVSD) of this facility. Instrumentation and methodology utilized in the operation of this clinical procedure was the Hemochron Response.

A motion to approve this request was made by Ms. Giannini with a second to the motion by Ms. Duncan. The motion carried.

5. Middle Tennessee Medical Center
400 N. Highland Avenue
Murfreesboro, TN 37133-1178

Attachment 1
Medical Laboratory Board
Point of Care Exemption Requests
January 15, 2004

Facility Representative: Marguerite West
Laboratory Administrative Director

This facility request was for Licensed Nursing Staff (RN's & LPN's) to perform and report myoglobin, CKMB and troponin 1 in the Emergency Department utilizing the Biosite Triage Cardiac Panel.

Dr. McDonald recused himself from this vote.

A motion to approve this request contingent upon correlation studies submitted to the administrative office by January 30, 2004 was made by Dr. Handorf. A second to the motion was made by Dr. Ferguson. The motion carried.

6. Erlanger Medical Center
975 East Third Street
Chattanooga, TN 37403

Facility Representative: Mary Bearden, MT (ASCP)
Laboratory Support Services Manager

This facility request was for Registered Nurses (RN's) in the Medical Ambulatory Care Unit (MACU) to perform and report sodium, potassium, chloride, CO₂, ionized calcium, BUN, hematocrit, creatinine, prothrombin time, blood gases and lactate utilizing the i-STAT instrument and methodologies.

A motion to approve this request was made by Dr. McDonald. A second to the motion was made by Dr. Handorf. The motion carried.

7. Diagnostic Laboratories-Vanderbilt University Medical Center
Department of Pathology
4605 TVC
Nashville, TN 37232-5310

Facility Representative: Teri Tubb
Point-of-Care Coordinator

Attachment 1
Medical Laboratory Board
Point of Care Exemption Requests
January 15, 2004

The request was made for the following exemptions:

1. Cardiopulmonary Perfusionists to perform and report activated clotting times (ACT's) in the Operating Rooms of Vanderbilt Children's Hospital utilizing the Hemachron Jr., Signature Instrument and methodologies.

A motion to approve this request was made by Dr. Handorf. A second to the motion was made by Dr. Ferguson. The motion carried.

2. The modification to an exemption granted in July 2001 to allow Care Partners as staff to perform and report hemoglobin A1c testing procedures in Suite D Children's Hospital Outpatient Center East utilizing the Bayer DCA 2000 Analyzer.

A motion to deny this request was made by Dr. McDonald. A second to the motion was made by Ms. Lahr. The motion carried.

3. Nurse Practitioners, Registered Nurses (RN's) and Licensed Practical Nurses (LPN's) to perform and report hemoglobin A1c testing procedures in the Medical Specialties Clinic of the Vanderbilt Clinic (TVC). The Bayer DCA 2000 Analyzer will be the instrument of choice for these testing procedures.

A motion to approve this request was made by Dr. McDonald with a second to the motion by Dr. Handorf. The motion carried.

INITIAL FACILITY LICENSES: REGIONAL SURVEYOR RECOMMENDATION

1. Laboratory Corporation of America Holdings
930 Madison Avenue Suite 500
Memphis, TN 38163

Medical Laboratory Director: Louisa Balazs, MD PhD
Anatomic Pathology

Specialties: Histopathology and Cytopathology

Surveyor: Mary Hamblen, Consultant II/Surveyor
West TN Regional Office

Ms. Hamblen was not at the board meeting and Ms. Karon Daniels recommended approval of this license based on an on- site survey.

Dr. Handorf recused himself from the discussion and vote.

A motion to approve this request was made by Dr. McDonald. A second to this motion was made by Dr. Ferguson. The motion carried.

2. LifeBlood/MidSouth
7505 Highway 64 Suite 109
Memphis, TN 38133

Medical Laboratory Director: Edward P. Scott, MD

Specialties: Spun Hct, Hgb by Copper Sulfate

Surveyor: Mary Hamblen, Consultant II/Surveyor
West TN Regional Office

In the absence of Ms. Hamblen, Ms. Daniels recommended approval of this license based on an on-site survey. A motion to approve this request was made by Ms. Giannini. A second to the motion was made by Ms. Hargrove. The motion carried.

Attachment 2
Initial Facility Licenses
Medical Laboratory Board
January 15, 2004

3. Erlanger East ABG Laboratory
Erlanger Health System
1755 Gunbarrel Road
Chattanooga, TN 37403

Medical Laboratory Director: Suresh Enjeti, MD
Pulmonology

Specialties: Arterial Blood Gases & pH

Surveyor: Julia Daniels, Consultant II/Surveyor
East TN Regional Office

A motion to approve this facility license was made by Dr. Handorf. A second to the motion was made by Ms. Stinnett. The motion carried.

4. The Center for Cytogenetics, Inc.
1719 West End Avenue Suite 403 E
Nashville, TN 37203

Medical Laboratory Director: Sugandhi A. Tharapel, PhD
Director-Cytogenetics

Specialties: Cytogenetics

Surveyor: Sandra S. Bogard, Consultant II/Surveyor
Middle TN Regional Office

A motion to approve this facility license was made by Dr. Ferguson. A second to the motion was made by Ms. Hargrove. The motion carried with Dr. Handorf voting against approval.

Attachment 2
Initial Facility Licenses
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5. StoneCrest Medical Center
200 StoneCrest Blvd.
Smyrna, TN 37167

Medical Laboratory Director: Terence T. Casey, MD
Anatomic/Clinical Pathology
Hematology

Specialties: Bacteriology, Parasitology (Limited), Virology (Limited), Mycology (Limited), General Immunology (Limited), Clinical Chemistry, Urinalysis, Hematology, Immunohematology, Histopathology (Limited to Frozen Sections), Arterial Blood Gases and pH, Wet Prep

Surveyor: Sandra S. Bogard, Consultant II/Surveyor
Middle TN Regional Office

Ms. Stinnett and Ms. Duncan recused themselves from the discussion and vote. A motion to approve this facility license was made by Dr. Handorf with a second to the motion by Dr. Ferguson. The motion carried.

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